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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/717,845	11/19/2003	Ruth A, Gjerset	049146-1001	9478
30542	7590	10/03/2007		
FOLEY & LARDNER LLP P.O. BOX 80278 SAN DIEGO, CA 92138-0278			EXAMINER LONG, SCOTT	
			ART UNIT 1633	PAPER NUMBER
			MAIL DATE 10/03/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/717,845

Applicant(s)

GJERSET ET AL.

Examiner

Scott D. Priebe, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 22,24-29 and 31-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22,24-29,31-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Claim Rejections - 35 USC § 103***

Claims 22, 24-29, and 31-35 remain rejected and claims 36-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roth et al., US 5,747,469 in view of: either or both of Lu et al. (Cancer Res. 62: 1305-1310, 01 March 2002) or Tango et al. (Hum. Gene Ther. 13: 1373-1382, 20 July 2002); Almond et al., WO 99/47690; and Teimann, WO 01/11063 for the reasons of record set forth in the Office action of 2/13/07.

Applicant's arguments filed 8/13/07 have been fully considered but they are not persuasive. Applicant argues that Lu et al. and Tango et al. carried out experiments where the amount of p53 and p14ARF vectors (genes) were not 1:1 as would be the case if both genes were on a single vector, and that this suggests placing both p53 and p14ARF genes on a single vector would not be obvious and there would not be a reasonable expectation of success. In response, Lu used a higher amount of the p53 vector and Tango used a lower amount of the p53 vector, each in relation to the p14ARF vector. In either case, the combination was significantly more effective than treatment with a p53 vector alone. Also, neither Lu nor Tango disclosed the expression efficiency of the transgene carried by each vector, i.e. comparison of the amount of vector used cannot be used to predict the ratio of p53 and p14ARF that were expressed in co-transfected cells. Neither reference explicitly teaches that either one should be in higher amount for the purpose of gene therapy; both teach that the combination therapy would be more effective

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than treatment with a p53 vector alone. Tiemann and Almond both teach that for gene combination therapies, including two therapeutic genes on the same vector in a bicistronic construct under control of one promoter is accepted practice in the art. Therefore, it is obvious to do so. Furthermore, Tiemann explicitly teaches a bicistronic construct such as that recited in the claims, specifically for treating cancer. Tiemann does not distinguish between treating cancer cells that have endogenous p53 from those which do not, and since there are only two possibilities here, one of skill in the art of cancer gene therapy would understand, especially in view of Lu and Tango, that the method of Tiemann could be practiced with success on cancers characterized by endogenous p53, as well as cancers characterized by lack of p53. Issues of whether in certain instances, e.g. with certain cell lines in culture, different ratios of p53 or p14ARF would work best does not detract from the clear indication in the art that the combination is superior to p53 alone or p14ARF alone, regardless of whether the target cells have or lack endogenous p53. Furthermore, in the context of gene therapy, Almond teaches different reasons why one should have both genes on a single vector rather than on separate vectors, including improving cotransfection efficiency and reducing toxic side effects. Consequently, the finding that placing both p53 and p14ARF genes on the same vector gave better results than using separate vectors is expected, not unexpected.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe, Ph.D. whose telephone number is (571) 272-0733. The examiner can normally be reached on M-F, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D. can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Scott D. Priebe/

Scott D. Priebe, Ph.D.  
Primary Examiner  
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